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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/380,200 01/30/95 BIRNSTIEL

M 0652.1080001

EXAMINER

HM12/0228

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NOLAN, F

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

02/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/380,200

Applicant
Birnstiel

Examiner
Patrick Nolan

Group Art Unit
1644



☒ Responsive to communication(s) filed on Nov 21, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-33 and 35-42 is/are pending in the application.

Of the above, claim(s) 3-7, 11, 12, 15, 16, 21-27, 30-33, 35, 37, and 42 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 8, 13, 14, 17-20, 28, 36, and 38-41 is/are rejected.

☒ Claim(s) 9, 10, and 29 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

1. This application is a continuation of 07/946,498.
2. Claims 1-33 and 35-42 are pending.
3. Claims 3-7, 11-12, 15-16, 21-27, 30-33, 35, 37 and newly added claim 42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 8, 13, 14, 17-20, 28, 36, 38-40 and newly added claim 41 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,166,320, of record, in view of U.S. Patent 5,144,019 and U.S. Patent 5,428,132, for reasons set forth in Paper No.42.

Applicant's arguments filed 11-21-00 have been fully considered but are not found persuasive.

Applicant argues that the '320 patent does not specifically direct one of skill in the art to make and use an antibody-polylysine-nucleotide conjugate but merely provides a list of millions of possible ligand binding agents to be used, wherein

antibody is one of them.

However, column 6, lines 1-14, discloses only three types of targeting agents, glycoproteins, antibodies or polypeptide hormones. This generic disclosure of three agents does not rise to the level of millions of possible components in which there is no direction to applicants claimed invention.

Further, Applicant argues there is no motivation or expectation of success in creating Applicant's claimed invention.

However, at the time of Applicant's invention, it was known to make and use antibody-polylysine-nucleotide conjugates for the delivery of and introduction of genes into mammalian cells, taught by the '320 patent, it was known to deliver and introduce ribozymes genes to CD4+ T cells with a liposome-ribozyme targeting system to treat HIV infected cells as taught by the '019 patent, it was known to deliver and transfect T cells with anti-CD3 antibody-polynucleotide conjugates as taught by the '132 patent and it was known that antibody-polylysine-polynucleotide conjugates were advantageous delivery systems to liposomes because it is difficult to control the leakage of contents of the liposome and to direct cell specificity as taught by the '320 patent and it was known that by noncovalently conjugating the polynucleotides to polylysine it allows for the polynucleotides to not be damaged or altered so successful in vivo endocytosis and expression of said polynucleotide can occur as taught by the '320 patent, so there was clear motivation to arrive at applicant's claimed invention by the combined teachings of the '019 patent, '132 patent and the '320 patent by creating a ribozyme targeting agent that is linked to anti-CD3 antibody by polylysine. As far as expectation of success in creating the conjugate, antibody conjugating methods were clearly known at the time of the invention as taught by the '132 patent and methods of linking polynucleotides to polylysine were taught by the '320 patent.

5. Claims 9-10 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final


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Art Unit: 1644

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action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.


Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
February 26, 2001